MAY - 3 2000

K000547

TECNIKA
Original Premarket 510(k) Notification: SUMMARY

Advanced Technology Research s.a.s.
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SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CTR 807.92

14.1 SUBMITTER INFORMATION

a.	Company Name:	Advanced Technology Research
b.	Company Address:	Via del Pescino 6 51100 Pistoia ITALY
c.	Company phone: Company Facsimile:	39 0573 364 254 39 0573 364 002
d.	Contact Person:	Dr. Poli Daniele General manager
e.	Date Summary Prepared:	February 15, 2000

14.2 DEVICE IDENTIFICATION

a.	Trade/Proprietary Names	ATR TECNIKA
b.	Classification Name:	Dental Handpiece and Accessories 21 CFR 872.4200

14.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
NOUVAG	TCM3000/ENDO	K981679	02/09/1999

14.4 DEVICE DESCRIPTION

The ATR Tecnika is a microprocessor driven micromotor used in dental drilling and tightening of various type of screw in dental implantation and in microsurgery. TECNIKA' s primary components are: 1) a console 2) a motor 3) a microprocessor 4) a foot pedal.
The ATR TECNIKA provides electronic control of reduction ratios, velocity and torque. The ATR TECNIKA can be programmed and retains up to nine programs in memory.
ATR TECNIKA is equipped also with a foot pedal for starting and stopping the motor.

14.5 SUBSTANTIAL EQUI VALENCE

The ATR Tecnika is substantially equivalent to the TCM3000/Endo in commercial distribution by Nouvag AG.
The fundamental technical characteristics of the ATR Tecnika are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission. The ATR TECNIKA and the predicate device have the same general intended use: microprocessor controlled dental drilling and torque controlled system. These devices also have very similar indications: dental implantation and oral microsurgery. These devices have the same principles of operation. The operator sets the motor speed, contrangle reduction rate and torque value and operates the drill by "motor" key on the console or by foot switch. The microprocessor of ATR TECNIKA and TCM3000/Endo implements the operator' s commands. ATR TECNIKA and TCM3000/Endo have very similar technological characteristics:

- Keys on the console for setting the motor speed, torque values, reduction ratios and starting and stopping the motor.

- A foot pedal for starting and stopping the motor.
- Motor's torque values are preset according to the selected contrangle reduction.
- Both require AC current.
- Both are microprocessor controlled.
- The devices are not supplied with drills or contra angles.
- Both devices can be used with any E-type contrangle.
- ATR TECNIKA and predicate device micromotors are autoclavable.

Thus, ATR TECNIKA and Nouvag TCM3000/Endo are substantially equivalent.

14.6 INTENDED USE

The ATR Tecnika is intended for dental drilling and tightening of various type of screw in dental implantation and in microsurgery.

14.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the ATR TECNIKA with the predicate device is provided within this submission.
The ATR Tecnika has adjustable speed and torque that are related to the reduction rate of handpiece selected. The ATR TECNIKA is programmable and retains the programs in memory. The micromotor has a standard E-Type coupling that will fit any E-Type contra angle.
ATR TECNIKA is equipped with a foot pedal for starting and stopping the motor.
The rotation of the micromotor can be set clockwise or counterclockwise.

The console houses two different audible alarm signals : one is activated automatically when the drill is going to reach the torque set level; the other is activated when the drill is turning in the reverse rotation.

On the rear panel is available a special input to connect the unit to a PC. When the ATR TECNIKA is connected to a PC all the unit is disarmed. The purpose of this connection is to update the default values of speed and torque.

ATR TECNIKA is equipped also with a micromotor "autoreverse" function. ("A/rev" key = Led On) This function acts as a torque control. TECNIKA will run at speed and reduced torque until the dynamic resistance exceed the set torque value. If this is reached , the rotation of the micromotor will automatically set for counterclockwise rotation and will return to clockwise rotation after two revolutions.

ATR TECNIKA is equipped also with a micromotor "shut-off" function. ("A/rev" key = Led Off) This function acts as a torque control. TECNIKA will run at speed and reduced torque until the dynamic resistance exceed the set torque value. If this is reached , the rotation of the micromotor will automatically stop.

ATR TECNIKA is equipped also with a alternate movement forward/ reverse when "F+R" Led is On.

14.8 PERFORMANCE DATA

The ATR TECNIKA was subjected the performance bench testing in accordance with applicable industry and clinical standards. Physical performance studies were conducted to verify that the ATR TECNIKA

conformed to applicable emission, immunity and electromagnetic compatibility standards in accordance with EN and IEC regulations. Results of the testing showed that the ATR TECNIKA perform as intended.

14.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Dr. Poli Daniele
General Manager
Advanced Technology Research
Via del Pescino 6
51100 Pistoia
ITALY

Re: K000547
Trade Name: ATR TECNIKA
Regulatory Class: I
Product Code: EFB
Dated: February 15, 2000
Received: February 18, 2000

Dear Dr. Daniele:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATR TECNIKA
Original Premarket 510(K) Notification

INDICATIONS FOR USE

510(K) Number: K000547 To be assigned by FDA

Device Name: ATR TECNIKA

Indications for use: To be used for dental drilling and tightening of the various Types of screws during dental implantation and microsurgery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

S. Shumel, DMD, MPA
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000547

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

CONFIDENTIAL